

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

BONEAU, Michael D.

Appl. No. 09/287,216

Filed: April 5, 1999

For: **Endovascular Support Device and  
Method**

Confirmation No.: 6024

Art Unit: 3738

Examiner: Jackson, S.

Atty. Docket: P106 DIV 3C  
(1737.2120097/DKSC)

**Information From Related Litigation**

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

Pursuant to the provisions of MPEP 2001.06(c), the Applicant brings to the attention of the Examiner information arising from litigation which may relate to the subject matter of the present patent application. By filing this paper the Applicant is making a good faith attempt to provide the U.S. Patent and Trademark Office with sufficient information to clearly inform the Office of the nature and substance of the issues delineated in § 2001.06(c) so that the Office can intelligently evaluate the issues and the need to ask for additional information or material. To the extent that the Office desires further material and/or additional information about any of the litigation described below, the Applicant will be pleased to provide such information to the extent that it can be done without violating any applicable protective orders.

As the Office is undoubtedly aware, it is common for a defendant in a patent infringement case to make numerous allegations to attempt to avoid liability. For example, it is typical for a defendant to allege that a patent is either invalid or that it was procured through fraud or inequitable conduct. It is also common for parties in a litigation involving

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patent rights to make allegations relating to both inventorship and ownership of a patent. It is also typical for these types of allegations to be unsuccessful, abandoned before trial and/or never pursued for lack of merit.

Outlined below is a general description of various actions involving either the general subject matter of the present patent application or the patent applications in the priority chain. The Applicant has attempted to fairly represent the allegations and position of the various adverse parties by providing representative pleadings, depositions or documents that describe the allegations and/or outline the position of the adverse party without inundating the Office with the inordinate amount of paper generated in these actions. For instance, the inventor Michael Boneau was deposed for numerous days in various of the actions discussed below. Thus, the documents provided herein are not intended to be a comprehensive compilation of *every* pleading, deposition or document that makes an allegation.

The Applicant disagrees with each of the allegations that have been asserted by the adverse parties in the litigations as described below. However, in accordance with the Applicant's understanding of MPEP 2001,06(c), the Applicant does not believe it is necessary and has not attempted in this document to provide a detailed refutation of every allegation.

### **Litigation Matters**

Allegations have been made in the following litigation matters:

1. ***Advanced Cardiovascular Systems v. Arterial Vascular Engineering, Inc. (In the United States District Court for the District of Delaware, Case No. 98-314-SLR)***  
***and***  
***Medtronic AVE, Inc v. Advanced Cardiovascular Systems (In the United States District Court for the District of Delaware, Case No. 98-80-SLR)***  
***and***  
***Advanced Cardiovascular Systems v. Arterial Vascular Engineering, Inc. (In the United States District Court for the District of Delaware, Case No. 98-316-SLR)***

These cases involve a series of three consolidated litigations that have been stayed until at least August 31, 2002. The first of the cases was filed on December 24, 1997 by Advanced Cardiovascular Systems (ACS) in the Northern District of California against Arterial Vascular Engineering (AVE, now Medtronic AVE, the assignee of the present patent application) alleging that AVE infringed U.S. Patent Nos. 5,421,955, 5,514,154, and 5,603,721. This case was transferred to the District of Delaware and was assigned Case No. 98-314-SLR.

On February 18, 1998, AVE filed an action in Delaware alleging that claims of the '955 patent, the '154 patent and the '721 patent were not infringed, were invalid and unenforceable. In addition, AVE alleged that ACS wrongly acquired confidential information from Michael Boneau and/or the prior assignees of the Boneau patent rights and that ACS infringed U.S. Patent No. 5,292,331 and U.S. Patent No. 5,674,278. Both the '331 and '278 patents are in the same chain as the present patent application. This case was assigned Case No. 98-80-SLR.

On April 10, 1998, ACS filed an action against AVE in the Northern District of California alleging that AVE infringed U.S. Patent No. 5,735,893. This case was also transferred to the District of Delaware and assigned Case No. 98-316-SLR. All three of these cases were consolidated under Case No. 98-80.

In the first filed case, Case No. 98-314-SLR, AVE filed a motion to disqualify ACS's lawyers. In a response dated September 18, 1998, ACS made certain allegations that the Applicant and Assignee of the present patent application wish to bring to the attention of the Office. A copy of the entire September 18 response is annexed hereto as **Exhibit 1**. We have also enclosed each of the Exhibits (Exhibits A-W) that were attached to the September 18 Response. While the Examiner's attention is directed to the entire document, the following comments may assist the Examiner in assessing its relevance. The Applicant believes that §§ 3 and 4 may be the most pertinent portions of this paper, although the Applicant strongly disputes the allegations made therein. § 3 on page 11 of **Exhibit 1** is entitled "Zig-Zag Stents Were Well-Known Before Boneau's Application Was Filed" and refers to Exhibit G, page 121 and Exhibit F of the September 18 Response. Exhibit G discusses a technique used with self-expanding stents that did not fully expand, which is known as the "Swiss Kiss." Exhibit F is the Gianturco '568 patent. The reasons why the invention claimed by the Applicant herein is clearly patentable over the art disclosed in these documents is fully addressed in the Reply filed herewith.

With respect to § 4 of **Exhibit 1** entitled "AVE Inappropriately Attempts to Compare the Boneau Device with Just an Isolated Portion of ACS's Stent," ACS attempts to address the interpretation of certain claims in the original '331 Boneau patent using its file history. While Applicant disagrees with ACS's interpretation of the prosecution history, Applicant does not believe that this prior application or its file history is applicable to the present case. As outlined in the Reply, the scope of the claims Applicant seeks is clear and *independent* from any arguments that may have been made in previous cases.

In the lawsuit filed by AVE (Case No. 98-80-SLR), ACS filed an Answer and Counterclaim which makes a number of allegations. This Answer and Counterclaim is annexed hereto as **Exhibit 2**. For Example, ACS alleges that certain patents (in the same chain as the present application) are invalid for failure to comply with 35 U.S.C. §§ 102, 103, 112, and 256 ( **Exhibit 2**, paragraph 120), are invalid for double patenting (**Exhibit 2**, paragraph 121), and that U.S. Patent No. 5,292,331 to Boneau is unenforceable for misrepresenting the testing and usefulness of a device described in the '331 patent, for misrepresenting the inventorship and for failing to disclose the best mode for carrying out the invention (**Exhibit 2**, paragraph 122). In addition, ACS alleges that certain information was withheld from the United States Patent and Trademark Office (**Exhibit 2**, paragraph 122). Similar allegations were made with respect to U.S. Patent Nos. 5,674,278 and 5,879,382 to Boneau (**Exhibit 2**, paragraphs 123 and 124). The inventor, Michael Boneau was deposed for numerous days in this case and in the case noted immediately below. Applicant and Assignee of the present invention deny each of these allegations. With respect to allegations of inequitable conduct, Applicant does not believe there were any misrepresentations made or material information knowingly withheld during the prosecution of any of the patents in the chain of priority.

2. ***Medtronic AVE, Inc. v. Boston Scientific Corp., SciMed Life Systems, Inc., Boston Scientific SciMed, Inc., and Medinol, Ltd. (In the United States District Court for the District of Delaware, Civil Action No. 98-478-SLR)***

This case was filed by AVE, now Medtronic AVE (the Assignee of the present patent application) in the United States District Court for the District of Delaware alleging infringement of U.S. Patent Nos. 5,292,331; 5,674,278; and 5,879,382 to Boneau. Each of

these patents is in the same chain as the patent application. Annexed hereto as **Exhibit 3** is a copy of Boston Scientific's Answer to Second Amended Complaint, Affirmative Defenses and Counter Claims. The parties to this action have agreed to a similar stay as in the ACS case described above except that the parties have agreed to brief a motion for summary judgment of non-infringement.

Boston Scientific has alleged that the '331, '278, and '382 patents are "invalid for failure to comply with one or more of the requirements of the United States Patent Statute, codified at title 35 of the United States Code, including but not limited to sections 101, 102, 103, 111, 112 and 116 thereof." **Exhibit 3**, pages 3 and 7. In addition, Boston Scientific alleged that these same patents were invalid under the doctrine of double patenting (**Exhibit 3**, pages 4 and 7), that Medtronic AVE is not the rightful owner of the patents (**Exhibit 3**, page 5 ) and that the '331, '278, and '382 patents are unenforceable due to inequitable conduct during prosecution of the applications that lead to the aforementioned patents, namely, allegedly failing to name one or more joint inventors (**Exhibit 3**, pages 5, 7-8 and 8-9). As noted above, the inventor Michael Boneau was deposed by the Defendants in this and the ACS case for numerous days. Applicant and Assignee of the present invention deny each of these allegations. With respect to allegations of inequitable conduct, Applicant does not believe there was any misrepresentation or material information knowingly withheld during the prosecution of any of the patents in the chain of priority.

**3. *Rodolfo DiMassa, M.D. et al v. Simon Stertz, M.D. et. al. (Case No. 222363).***

This lawsuit, which is pending in the Superior Court of California, was brought by Rodolfo DiMassa and Karl Nigg against Simon Stertz, Michael Boneau (the inventor of

the present patent application), Medtronic AVE, Inc (the Assignee of the present invention) and Stentcor International, Inc. and alleges breach of contract, breach of covenant of good faith and fair dealing, breach of fiduciary duty, misappropriation of trade secrets, unfair competition, intentional misrepresentation, concealment, nondisclosure, unjust enrichment and breach of confidence.

In an amended complaint filed on February 1, 2000 (a copy of which is annexed hereto as **Exhibit 4**), DiMassa, *et al.* allege that "[i]n late 1986 and early 1987, Dr. DiMassa conveyed to Defendant Stertzer several new ideas Dr. DiMassa had for creating an expandable stent, including use of an expandable wire mesh stent, a single wire stent in a sinusoidal design, and use of a heat expanding stent in a coil design made out of memory metal." DiMassa Amended Complaint, paragraph 35. In addition, DiMassa *et al.* allege that the same ideas were conveyed to Michael Boneau, the Applicant of the present patent application. *See*, DiMassa Amended Complaint, paragraph 36. Finally, DiMassa *et al.* allege that Michael Boneau "fail[ed] to promptly execute a specific assignment of title to Stentcor for the inventions claimed in the Boneau patents...and instead assigning these rights to competitors of Stentcor". DiMassa Amended Complaint, paragraph 63.

In a document captioned "Rudolfo DiMassa's Supplemental Answers to Defendant Medtronic Arterial Vascular Engineering Inc.'s First Set of Specially Prepared Interrogatories" (a copy of which is annexed hereto as **Exhibit 5**), Dr. DiMassa alleges that his research "was used by defendants in developing the Boneau stent." Dr. DiMassa goes on to say that he "cannot be more specific due to defendants' fraudulent concealment of their use of Dr. DiMassa's research." *See*, Supplemental Answers, page 7.

In a document captioned "Declaration of Paul Bonneau, Jr". (a copy of which is annexed hereto as **Exhibit 6**),<sup>1</sup> Paul Bonneau, Jr. alleges that:

[i]n late 1986 or very early 1987, I recall talking to my brother Michael about various ideas for an expandable stent design. One of the designs we discussed at this time was a sinusoidal design. I suggested to Michael that we take a ring or a straight wire with a width of 10/1000 and bend it into peaks and troughs, so that it could be compressed and expanded. I am not sure where the idea of a sinusoidal design came from, but I am the one who came up with the idea of bending a straight wire or a wire ring. I suggested that we use the same surgical stainless steel and finishing technique currently used on the DiMassa Sleeve.

Declaration of Paul Bonneau, Jr., paragraph 8. This same paragraph 8 was discussed in a January 9, 2001 deposition of Paul Bonneau, Jr. at which time Paul Bonneau, Jr. stated that paragraph 8 of his declaration was incorrect in that he did not suggest starting with a *ring* and bending it as stated in the third sentence of paragraph 8. *See*, pages 67-68 of Deposition Transcript of Paul Bonneau, Jr. annexed hereto as **Exhibit 7**.

The veracity of Paul Bonneau, Jr.'s declaration was eroded further in the following sworn testimony:

Question: And did you talk about bending it into peaks and troughs as stated in your declaration?

Answer: No

Deposition Transcript of Paul Bonneau, Jr., page 88.

Paul Bonneau, Jr. went on to explain at page 88-89 that "we discussed bending it [a straight wire], but we didn't discuss actually bending it into a certain configuration. So that

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<sup>1</sup>Paul Bonneau, Jr. is the brother of the Applicant, Michael Boneau. The Examiner may observe that the Declaration spells Bonneau with a double "n" while the inventor's last name has a single "n". Paul Bonneau, Jr. has testified that his last name sometimes has been spelled with a single "n" and sometimes with a double "n". Michael Boneau has testified similarly. To avoid confusion, Paul Bonneau, Jr.'s name will be spelled consistently throughout this paper.



is wrong. It is my fault." This was reiterated on page 89 of his deposition when Paul Boneau, Jr. stated that "we didn't know exactly which configuration to bend it into. . . ."

Michael Boneau was also deposed for several days in this case. Applicant and the Assignee believe that the inventorship of the present application is correct and vigorously dispute any alleged contrary contention.

**4. *Azam Anwar, M.D. et al v. Arterial Vascular Engineering, Inc, et. al (In the District Court of Dallas Texas, 298<sup>th</sup> Judicial District, Case No. 96-05323-M).***

This lawsuit is pending in the District Court of Dallas Texas by Azam Anwar, M.D. and Benito Hidalgo, (both brought the action individually and on behalf of Endovascular Support Systems, Inc., "ESS", a prior owner of the Boneau patent rights) alleging fraud, misrepresentation, violations of state security laws, control person and aider-and-abetter liability, civil conspiracy, breach of fiduciary duty, constructive fraud, breach of contract, unjust enrichment, and breach of covenant of good faith and fair dealing. A copy of the Plaintiffs' Eighth Amended Petition is annexed hereto as **Exhibit 8**. In the Petition, the plaintiffs contend that in 1989, Benito Hidalgo, working with Michael Boneau and Simon Stertzer, began developing a stent that was intended to be used for coronary disease. According to the Petition, "[t]he stent that was ultimately developed became known as the 'Boneau stent', which ultimately became the technical and legal foundation of AVE's current stent products. A key design feature of the stent, the helical joiner method, was the specific idea of Hidalgo." Eighth Amended Petition, paragraph 14. The petition goes on to allege that the "design was a key feature that became part of the patent that was ultimately awarded by the United States Patent Office. The plaintiffs allege that each of the stents manufactured or sold by AVE have incorporated the design, features, processes, and/or

methods defined as 'Inventions' owned by ESS." Eighth Amended Petition, paragraph 14. Mr. Hidalgo claimed in a deposition that he believed he was the first one who brought up the "z" or "zig-zag" type of design for use in a stent. *See also*, Answers Nos. 1 and 2 of "Plaintiff Benito Hidalgo's First Amended Objections and Answers to Defendant Gerald Dorros M.D.'s Second Set of Interrogatories" in which Mr. Hidalgo makes statements regarding his alleged contributions to a stent design. These Objections are annexed hereto as **Exhibit 9**. To the extent the statements made relating to the "helical joinder method" are understood, they do not appear to address the claims in the present application.

The Petition also states that "Plaintiff Anwar met Stertz, Hidalgo and Miller while he was on a fellowship in California in 1990", which of course is after the August 24, 1989 filing date of the first Boneau application. Eighth Amended Petition, paragraph 16. Anwar contradicted this statement in his deposition where he testified he first met Simon Stertz and Hidalgo in "July of 1989." Deposition Transcript of Azam Anwar 01/09/97, p. 13, lines 2-3, p. 14, lines 14-16 annexed hereto as part of **Exhibit 10**. This Exhibit consists of pages from various depositions of Azam Anwar in this case. Anwar also testified that he believed that Boneau and Ben Hidalgo invented the Boneau stent, that he was not sure of Dr. Stertz's exact involvement, and that he did not have any first hand knowledge of Hidalgo's alleged contribution. Deposition Transcript of Azam Anwar 01/09/97 p. 18, lines 2-11, p. 18, line 13 – p. 20, line 12, annexed hereto as part of **Exhibit 10**. *See also*, "Plaintiff Azam Anwar, M.D.'s First Amended Objections and Answers to Defendant John Miller's Second Set of Interrogatories", Answer 1 as it relates to Responses 106 and 162. These answers are annexed hereto as **Exhibit 11**. After testifying that based upon his experience with Palmaz stents he believed that using "several stents was probably not a great idea, meaning more

than – putting more than three or four stents in an artery led to problems down the road “Anwar testified that he brought up with Dr. Stertzer the “concept” of using multiple stents as “a building block, quote/unquote ‘Tonka Toys’. Deposition transcript of Azam Anwar 3/10/97 p. 60, line 17-p. 63, line 24; p. 130, line 16-p. 133, line 5. Anwar's lack of credibility concerning his belated adverse inventorship claims is apparent as he testified that despite speaking to Michael Boneau on many occasions, he never discussed with him whether Mike Boneau is “the sole inventor of the stent” and he does not recall having ever “talked to Mike Boneau about what role, if any, Ben Hidalgo had in the invention or development of the Boneau stent.” Deposition transcript of Azam Anwar 03/10/97 p. 125, line 17 – p. 129, line 11, **Exhibit 10**. Anwar also testified, without qualification that “Mike Boneau invented the stent.” Azam Anwar deposition transcript 3/10/97, p. 167, lines 6-20. Indeed, in subsequent testimony, Anwar made it clear that he doesn't recall Hidalgo claiming to have contributed to the Boneau invention until they decided to file a lawsuit in 1996. Deposition transcript of Azam Anwar 3/12/97, p. 355, line 9 – p. 357, line 22. Applicant and the Assignee believe that the foregoing demonstrates the inherent inconsistencies in the various belated and self-serving adverse inventorship claims.

In this action, certain investors claimed that they did not receive fair value for their rights in ESS. Thus, they contend that the value of ESS was strongly associated with the intrinsic value of the Boneau invention. As part of its defense to this securities fraud action, the Assignee of the present invention contends that the value of the Assignee company is due to more than merely the invention of the Boneau stent, the subject matter of the present invention. Specifically, in order to commercialize the Boneau invention, the Assignee had to, among other things, set up a large scale manufacturing facility, take steps to ensure

quality control, obtain FDA approval, set up distribution networks and undertake marketing efforts.

As noted above, Applicant and Assignee of the present invention deny each of the allegations relating to inventorship, and believes that the originally named inventor Michael Boneau is the true and correct inventor of the claimed invention. The Examiner may also note that the claims of inventorship by various adversaries are not only inconsistent with Michael Boneau's claim of inventorship but are also inconsistent with each other. Michael Boneau was also deposed in this action.

5. *Inflow Dynamics and SciMed Life Systems v. AVE (Nullity Proceeding 4 Ni 33/99 joined with 4 Ni 41/99)*

European Patent 0 417 928 claims priority to U.S. Patent Application Serial No. 398,180, now U.S. Patent No. 5,292,331 to Boneau, the same application from which priority in the present application is claimed. After AVE sued for infringement of the German counterpart of this European patent, nullity actions were brought by both Inflow Dynamics and SciMed Life Systems in Germany. A copy of the Nullity decision revoking the European patent in Germany is attached as **Exhibit 12**. An English translation of the Nullity decision is attached as **Exhibit 13**. Applicant believes that this decision is erroneous and is being appealed.

In any event, the decision of a German tribunal is not relevant to the present case because it is based on foreign patent law and because the claims are not the same as the claims in the present U.S. Application. See *Medtronic, Inc. v. Daig Corp.*, 789 F.2d 903 (Fed. Cir. 1986). However, out of an abundance of caution, the Applicant has brought this case to the attention of the U.S. Patent and Trademark Office to ensure that the Office is

aware of the actions of the German Court in a related patent application. In addition it is believed that the decision is incorrect and its reasoning is flawed under U.S. law as further discussed in the Reply submitted herewith.

**6. *Cordis Corporation v. Medtronic AVE, Inc. et al. (D. Del. Civ. Action 97-550 SLR Consolidated with Other Cases)***

This is an action in which the alleged owner and former exclusive licensee of certain balloon expandable stent patents filed in the name of Julio Palmaz and/or Richard Schatz brought a patent infringement action against Medtronic AVE. The Medtronic AVE products which were the subject of this litigation are also products intended to be covered by the claims of the present application. The action was filed in October, 1997, and after three years of intensive discovery, a jury trial was held in November 2000. The jury found that Medtronic AVE infringed certain claims of U.S. Patent No. 4,739,762 to Palmaz and U.S. Patent No. 5,195,984 to Schatz, which were not proved to be invalid by clear and convincing evidence as Medtronic AVE contended. Medtronic AVE believes the jury verdict is erroneous and various post trial motions seeking judgment as matter of law and/or a new trial, and a ruling of unenforceability for inequitable conduct are pending.

As the Examiner knows, the Palmaz '762 patent was used by the Examiner as the basis of a rejection in the Office Action dated October 18, 2000.

While this litigation does not directly bear on the patentability of the present claims, as discussed during the interview, the Applicant wishes to bring to the attention of the Office an argument made by the Assignee of the present application which might, at first blush, be regarded as inconsistent with the arguments for patentability made in the Reply filed herewith. Specifically, the Schatz patent relates to a series of connected stents. The stents

which are connected are of the type disclosed by the Palmaz '762 patent. Medtronic AVE took the position that certain claims of the Schatz patent were unpatentable because it would have been obvious under 35 U.S.C. § 103 to attach together a series of the Palmaz '762 balloon expandable stents in light of Gianturco's teaching of attaching self-expanding stents together. This position of Medtronic AVE was rejected by the jury. Annexed hereto as **Exhibit 14** is a copy of the trial testimony of Arina Van Breda, an expert hired by Medtronic AVE, who testifies regarding Medtronic AVE's obviousness argument.

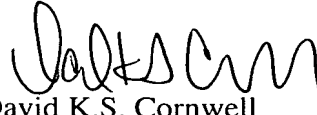
While AVE took numerous other positions over the course of this litigation, they are not believed to be relevant to this application. However, out of an abundance of caution, attached as **Exhibit 15** are two sets of interrogatory responses from this litigation which will give the Examiner an appreciation of the major positions Medtronic AVE took in this case. Again, the Applicant will attempt to provide further information if desired. Michael Boneau was also deposed in this case.

### **Conclusion**

Applicant has made a good faith attempt to bring to the attention of the Office, the general nature of the litigation which may relate to the present patent application, as well as the major positions and allegations of the parties. The Applicant strongly denies each of the adverse allegations made in the above discussed cases and contend that they lack merit. To the extent that the Office needs or wants additional materials or information or both, the Applicant would be pleased to provide the same if it can do so consistent with applicable protective order obligations.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read 'D.K.S. Cornwell', written in a cursive style.

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Date: June 11, 2001  
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\*LIMITED TO MATTERS  
AND PROCEEDINGS BEFORE  
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June 11, 2001

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**Attn: Examiner S. Jackson**  
**Art Unit: 3738**

Re: U.S. Utility Patent Application  
Appl. No. 09/287,216; Filed: April 5, 1999  
For: **Endovascular Support Device And Method**  
Inventor: Michael D. Boneau  
Our Ref: P106 DIV 3C (1737.2120007/DKSC)

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Reply Under 37 C.F.R. § 1.111, including Exhibits A-J;
2. Information From Related Litigation, including Exhibits 1-15, of which: Exhibit 1 includes Exhibits A-W; Exhibit 4 includes Exhibit A; Exhibit 6 includes Exhibits D1-D3, and Exhibit 12 includes: Plaintiff's Exhibits 3, 5, 6, 100, 143 and 207, and Defendant's Exhibits AVE 0084, 134, 359, 364, 461, 1224, 3301, 3303 and 3961;
3. Second Supplemental Information Disclosure Statement;
4. Form PTO-1449 (11 sheets);



Commissioner for Patents

June 11, 2001

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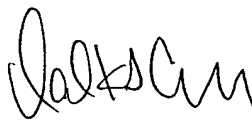
5. Copies of 130 references cited therein and two English translations of SU 660689 (Ref. No. AL2), and one English translation of Ref. No. AZ11; and
6. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this letter is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



David K. S. Cornwell  
Attorney for Applicant  
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DKSC:hmb  
Enclosures